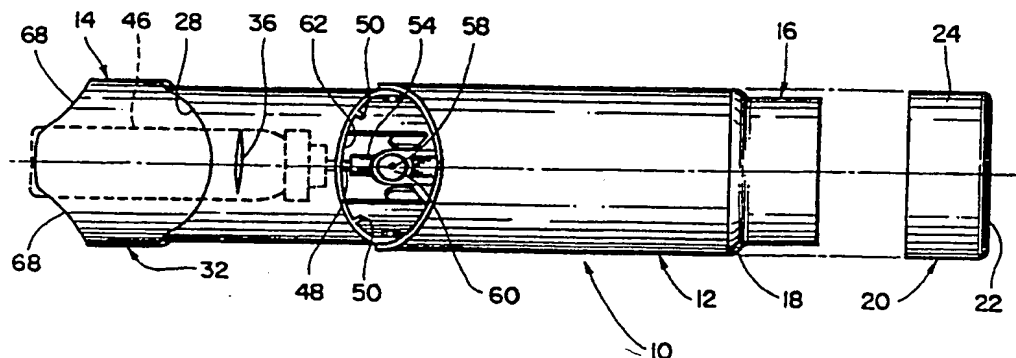




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>5</sup> : A61M 11/00, 15/00, B67D 5/06 B65D 83/00	A1	(11) International Publication Number: <b>WO 92/20391</b>
		(43) International Publication Date: 26 November 1992 (26.11.92)
<p>(21) International Application Number: PCT/US92/03945</p> <p>(22) International Filing Date: 12 May 1992 (12.05.92)</p> <p>(30) Priority data: 703,646 21 May 1991 (21.05.91) US</p> <p>(71) Applicant: ABBOTT LABORATORIES [US/US]; CHAD-0377/AP6D-2, One Abbott Park Road, Abbott Park, IL 60064-3500 (US).</p> <p>(72) Inventors: ADJEI, Akwete, L. ; 38770 Red Oak Terrace, Wadsworth, IL 60083 (US). SHERRY, Lois, R. ; 23526 Elm Road, Lincolnshire, IL 60069 (US). DANKS, Barbara, A. ; 445 Woodland, Greers Ferry, AR 72067 (US).</p>		<p>(74) Agents: GORMAN, Edward, Hoover, Jr. et al.; Abbott Laboratories, CHAD-0377/AP6D/2, One Abbott Park Road, Abbott Park, IL 60064-3500 (US).</p> <p>(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), HU, IT (European patent), JP, KR, LU (European patent), MC (European patent), NL (European patent), NO, PL, RU, SE (European patent).</p> <p>Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</p>

(54) Title: AEROSOL INHALATION DEVICE



## (57) Abstract

A pocket size, two-part aerosol inhalation device (10) wherein a medicament canister housing (14) formed of plastic is telescopically received in a plastic expansion chamber (12) having an elliptical cross section in a storage mode of the device and wherein the canister housing is connected to the expansion chamber by pin-and slot means (38, 40) whereby it is first slidable into a fully extended position relative to the expansion chamber after which it may be pivoted relative thereto into an angular operable position in which a spray orifice (58) provided therein is aligned axially with the axis of the expansion chamber whereby medicament released from the canister leaves the spray orifice with a vortex movement which slows down the aerosolized medicament sufficiently that the percentage thereof reaching the deepest portion of the lungs is maximized and the percentage thereof which merely impacts against the back of the throat is minimized.

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**AEROSOL INHALATION DEVICE****BACKGROUND OF THE INVENTION**

5           This invention relates to a two-part aerosol inhalation device which maximizes the delivery of a medicament, such as an LH-RH analog or other peptide, into the deepest part of the lung where it becomes most effective. With most inhalers of the type wherein a pressurized canister of medicament is mounted in a cylindrical holder, one end of which is intended to be pointed toward a patient's open mouth, the  
10           medicament is directed from the canister and through the cylindrical holder at such a high velocity that too high a percentage of the medicament merely impacts as relatively large particles against the back of the patient's throat with only a small percentage of the medicament finding its way into the deepest part of the patient's lung. Such pocket inhalers are well known in the art, including several which are of two-part  
15           construction, namely U.S. Patent Nos. 3,739,950; 3,927,806; 3,994,421; 4,130,116; and 4,637,528; none of which, however, provide the effective and efficient medicament delivery results which are most beneficial to a patient having a lung disorder requiring maximization of the delivered dose to be deposited in the deepest portion of the lung for absorption into the circulatory system.

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**SUMMARY OF THE INVENTION**

          The present invention is directed to an improved design for an aerosol inhalation device which effectively delivers a larger percentage of a medicament, especially of a poorly-absorbed drug such as a peptide, to the deepest part of a patient's lungs than is  
25           delivered by currently available inhalers. The new and novel design is characterized by an elongated expansion chamber and a canister housing, both of which are elliptical in cross-section, which are interconnected in a manner such that the canister housing, in which a pressurized canister of medicament is received, is telescopically

in axial alignment with the longitudinal axis of the elliptical expansion chamber. When a dosage of the pressurized medicament is released from the canister by manual inward movement of the canister relative to the canister housing in a well-known manner, the dosage exits the orifice passage at a very high velocity. Because of the elliptical cross-sectional configuration of the expansion chamber, the medicament dosage exits the orifice passage with a vortex movement which slows down the medicament particles and minimizes aggregation thereof whereby there is less impactation of the medicament particles against the back of the throat and maximization of the amount of the medicament deposited in the deepest portions of the lungs for final absorption into the circulatory system.

An object of the present invention is to provide a new and improved aerosol inhalation device.

Another object of the present invention is to provide such an aerosol inhalation device which is characterized by a pressurized medicament canister housing which is connected to an elongated expansion chamber which is elliptical in cross section whereby the velocity of the medicament particles is sufficiently slowed down so that a greater amount thereof is delivered into the deepest portion of the lungs rather than being impacted against the back of the throat.

Yet another object of the present invention is to provide such an aerosol inhalation device wherein an orifice passage through which each dosage is discharged into the expansion chamber has an axis which is aligned with the longitudinal axis of the elliptical expansion chamber whereby the medicament particles are discharged into the expansion chamber with a vortex movement.

A further object of the present invention is to provide such an aerosol inhalation device wherein the canister housing is pivoted into an angular operable position relative to the expansion chamber with the preferred obtuse angle therebetween being approximately 110°.

A still further object of the present invention is to provide such an aerosol inhalation

**BRIEF DESCRIPTION OF THE DRAWINGS**

The elements which are believed to characterize the invention are set forth in the appended claims. The invention itself together with the foregoing objects, features, and advantages thereof, and others, will be best understood by reference to the following detailed description taken in conjunction with the drawing, in which:

5 FIG. 1 is a top plan view of a preferred embodiment of an aerosol inhalation device embodying the invention when in its compact storage mode;

FIG. 2 is a top plan view of the device of Fig. 1 with the mouthpiece protective cap removed and with the canister housing in its intermediate fully-extended position

10 relative to the expansion chamber and just prior to pivoting of same into its operable position;

FIG. 3 is a side elevational view of the device of Figs. 1 and 2 with the mouthpiece cap removed and with the canister housing pivoted into its operable position;

15 FIG. 4 is an end elevational view of the device as shown in Fig. 3 and taken generally along the line 4-4 of Fig. 3;

FIG. 5 is a longitudinal sectional view taken generally along the line 5-5 of Fig. 4;

FIG. 6 is a longitudinal sectional view taken generally along the line 6-6 of Fig. 3 but with the device in its intermediate fully-extended position of Fig. 2;

20 FIG. 7 is a fragmentary sectional view taken generally along line 7-7 of Fig. 6 but with the valve stem housing and canister supporting ribs not shown; and

FIG. 8 is an end elevational view taken generally along line 8-8 of Fig. 3 but with the expansion chamber not shown.

25 **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT**

A preferred embodiment of the present invention comprises a compact, pocket or purse-size aerosol inhalation device 10, as illustrated in Fig. 1, which opens up into an operable mode, as illustrated in Fig. 3. The device 10 comprises an elongated

expansion chamber 12, the canister housing 14, and the mouthpiece cap 20 are all molded of appropriate plastic materials. At the open end of the expansion chamber 12 opposite the mouthpiece end thereof, the upper and lower wall portions are scooped inwardly, as at the generally concave rear edges 28 and 30 respectively, thereof, for purposes that will be discussed hereinafter. However, to provide a smooth-walled pocket or purse aerosol inhalation device 10 when the canister housing 14 is in its storage mode telescopically received within the expansion chamber 12, the canister housing 14 is provided at its outer end with a saddle-shaped outwardly offset wall portion 32 having a configuration which complements and mates with the rear end configuration of the expansion chamber 12. Detent means in the form of shallow upper and lower transverse grooves 34 formed on the inner surface of the expansion chamber 12 and transverse ridges 36 provided on the non-offset upper and lower side walls of the canister housing 14 serve to retain the canister housing 14 in its Fig. 1 storage position.

Pin and slot means are provided for connecting the canister housing 14 to the expansion chamber 12 with a pair of diametrically opposite, longitudinally extending slots 38 being provided in the side walls of the canister housing 14 and with a pair of diametrically opposite pins 40 projecting inwardly from the rear ends of the non-scooped side walls of the expansion chamber 12 and through the slots 38. The pins 40 have enlarged heads 42 for retaining the pins 40 in the slots 38 with the rear ends of the slots 38 being enlarged, as at 44 to facilitate assembly of the canister housing 14 to the expansion chamber 12.

The rear end of the canister housing 14 is open to permit insertion therein of pressurized canisters 46 of suitable medicaments for the treatment of lung disorders, such as peptides, an example of which is leuprolide. The canister 46 is of a known type having a hollow valve stem 48 which is biased outwardly of the front end of the canister 46 in axial alignment with the longitudinal axis thereof. The canister 46 is centered in the housing 14 by a series of four longitudinally extending ribs 50 which

54 is provided with an axial bore 56 which is axially aligned with the longitudinal axis of the canister housing 14 and is adapted to sealingly receive the valve stem 48 of the pressurized canister 46 therein. A laterally disposed orifice passage 58 is formed in the valve stem housing portion 54 and intersects the axial bore 56 therein at an obtuse  
5 angle of approximately  $110^\circ$  or a conversely acute angle of approximately  $70^\circ$ . The exit end of the passageway 58 is flared or generally conical in configuration, as at 60, and faces generally upwardly of the canister housing 14 as viewed in Figs. 2 and 6. An upper side wall portion of the canister housing 14 opposite the flared exit end 60 of the orifice passage 58 is either broken or cut away or left open during the molding process,  
10 as at an edge 62, for reasons that will become obvious hereinafter.

To use the aerosol inhalation device 10 of the present invention when same is in its storage mode as shown in Fig. 1 with a pressurized canister 46 of medicament disposed within the elliptical canister housing 14, with the elliptical canister housing 14 being telescopically retained within the elliptical expansion chamber 12, and with  
15 the cap 20 mounted on the mouthpiece configuration 16, the cap 20 is first removed and the canister housing 14 is slidably moved to its fully-extended position generally axially aligned with the expansion chamber 12, as shown in Figs. 2 and 6, the pins 40 being in engagement with the non-enlarged inner ends of the slots 38.

The upper and lower side wall scooped out portions, at 26 and 28, of the  
20 expansion chamber 12 and the cut-away upper side wall portion, at 62, of the canister housing 14 permit pivoting movement of the canister housing 14 relative to the expansion chamber 12 into the operable mode or position shown in Figs. 3, 4, 5 and 8 of the drawings wherein the obtuse angle therebetween is approximately  $110^\circ$  and with the acute angle between the longitudinal axes thereof being approximately  $70^\circ$ . This  
25 pivoting angle between the expansion chamber 12 and the canister housing 14 in the operable mode of the aerosol inhalation device 10 is pre-determined by interference contact between 1) the forward edge of the curved end wall 52 of the canister housing 14 with the inner surface of the lower side wall of the expansion chamber 12, as at 64

46 and through the orifice passage 58 into the elliptical expansion chamber 12, the movement of the aerosolized medicament with this structural arrangement is a vortex movement which minimizes aggregation of the medicament particles and slows down their movement so as to minimize impaction of same against the back of the user's throat while maximizing the amount of the medicament delivered to the deepest portions of the lungs.

Although the obtuse angle between the canister housing 14 and the expansion chamber 12 in the operable mode of the preferred embodiment of the device 10 disclosed herein is 110°, it is noted that other obtuse angles could come within the scope of the invention, for instance angles from 135° to 90°, as long as the angle between the axis of the orifice passage 58 and the longitudinal axis of the canister housing 14 is such that in the operable position of the device the axis of the orifice passage 58 is axially aligned with the longitudinal axis of an elliptical cross-section expansion chamber.

It is noted that for most effective operation of this aerosol inhalation device 10, auxiliary air inlet ports 72 are provided in the lower side wall of the canister housing 14 rearwardly of the flared exit end 60 of the orifice passage 58 and on opposite sides thereof as is best illustrated in Figs. 2, 3, 4, 6 and 8. As shown in Figs. 1 and 2, the rear end of the pressurized canister of medicament 46 is approximately flush with the rear edge of the canister housing 14 when inserted therein. This arrangement minimizes inadvertent actuation of the canister 46 and unintended release of the medicament. As an aid to activating the canister 46 to release medicament therefrom by moving same inwardly of the housing 14, the side edges of the housing 14 are cut away inwardly, as at 68, to facilitate inward movement of a finger engageable with the end of the canister 46.

As a further aid to actuating the device 10, a thumbreceiving depression 70, which may be roughened or knurled, is provided in the outer surface of the inner end wall 52 of the canister housing 14.



Accordingly, it is intended that all such changes and modifications be covered by the appended claims and their equivalents.

WE CLAIM:

1. An aerosol inhalation device for maximizing delivery of medicament into the lung, said device comprising an elongated expansion chamber which is elliptical in cross-section, a mouthpiece configuration provided at one end thereof, a canister housing associated with said elliptical expansion chamber for receiving a  
5 pressurized canister of medicament, an orifice passage in said canister housing for axial alignment with the longitudinal axis of said expansion chamber and having an outwardly flared exit end configuration, and passage means in said canister housing between said pressurized canister and said orifice passage, medicament released from  
10 said pressurized canister exiting said orifice passage at high velocity with said elliptical configuration of said expansion chamber causing a vortex movement of the medicament particles and both a decrease in the velocity thereof and a minimizing of the tendency of said particles to aggregate whereupon a lesser amount of said medicament merely impacts against the back of a patient's throat and a greater amount of said medicament reaches the deepest part of the patient's lungs.  
15
2. The aerosol inhalation device of claim 1 wherein said canister housing is also elliptical in cross section.
3. The aerosol inhalation device of claim 2 wherein said expansion chamber and said canister housing are interconnected in a manner such that they are both slidable and pivotal relative to one another to permit storage of said canister housing within said expansion chamber.  
5
4. An aerosol inhalation device for maximizing delivery of medicament into the lung, said device comprising an elongated expansion chamber elliptical in cross-section, an elongated canister housing telescopically slidable into said expansion chamber and adapted to have a pressurized canister of medicament disposed therein  
5 with a valve stem projecting from one end thereof, a valve-stem-receiving bore provided in said canister housing for receiving said canister valve stem, a laterally disposed orifice passage formed in said canister housing and intersecting the valve-stem-receiving bore thereof with the axis of said orifice passage being disposed at an angle greater than 90° from the axis of said valve-stem-receiving bore and with an exit  
10 end of said orifice passage being generally flared outwardly, means connecting said canister housing to said expansion chamber to permit movement of said canister

housing from a storage position telescoped within said expansion chamber to an axially-aligned, fully-extended position, said canister housing being pivotal only when in said fully-extended position through an angle less than 90° into an operable position wherein the axis of said orifice passage is disposed in axial alignment with a longitudinal axis of said elliptical expansion chamber, and air inlet means provided in said canister housing adjacent said orifice passage.

5. The aerosol inhalation device of claim 4 wherein interference means are provided between said expansion chamber and said canister housing for limiting both telescopic movement of said canister housing into its storage position within said expansion chamber and said pivotal movement therebetween.

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6. The aerosol inhalation device of claim 4 wherein a mouthpiece configuration having lip-engageable shoulder means is provided at one end of said expansion chamber and wherein a removable cap is provided for said mouthpiece configuration.

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7. The aerosol inhalation device of claim 4 wherein said connecting means is characterized by pin means provided on said expansion chamber and by slot means provided in said canister housing.

8. The aerosol inhalation device of claim 4 wherein the angle between the axis of the orifice passage and the axis of the valve-stem-receiving bore is approximately 110° and wherein said angle through which said canister housing is pivotal relative to said expansion chamber is approximately 70°.

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9. The aerosol inhalation device of claim 4 wherein longitudinally extending, circumferentially spaced rib members are provided in said canister housing for supporting said canister of medicament therein.

10. An aerosol inhalation device for maximizing delivery of medicament into the lung, said device comprising an elongated expansion chamber elliptical in cross-section, a mouthpiece configuration provided at one end of said expansion chamber, an elongated canister housing telescopically receivable in said expansion chamber and open at one end for receiving therein a pressurized canister of

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medicament having a valve stem projecting from one end thereof, said canister housing having a valve-stemreceiving portion, a laterally disposed orifice passage formed in said valve-stem-receiving portion and intersecting a valve-stemreceiving bore thereof with the axis of said orifice passage being disposed at an angle to the axis of said valve-stemreceiving bore, pin-and-slot means connecting said canister housing to said expansion chamber whereby to permit movement of said canister housing from a storage position telescoped within said expansion chamber to an axially-aligned, fully-extended position, said canister housing being pivotal only when in said fully-extended position into an operable position wherein the axis of said orifice passage is disposed in axial alignment with the longitudinal axis of said elliptical expansion chamber, interference means between said expansion chamber and said canister housing limiting relative pivotal movement therebetween, and air inlet means provided in a side wall portion of said canister housing adjacent said orifice passage in said valvestem-receiving portion thereof.

11. The aerosol inhalation device of claim 10 wherein interference means are provided between said expansion chamber and said canister housing for limiting inward telescopic movement of said canister housing into its storage position within said expansion chamber.

12. The aerosol inhalation device of claim 10 wherein said mouthpiece configuration is provided with lip-engageable shoulder means, and wherein a removable cap is provided for said mouthpiece configuration.

13. The aerosol inhalation device of claim 10 wherein said pin-and-slot connecting means is characterized by pin means provided on said expansion chamber and by slot means provided in said canister housing.

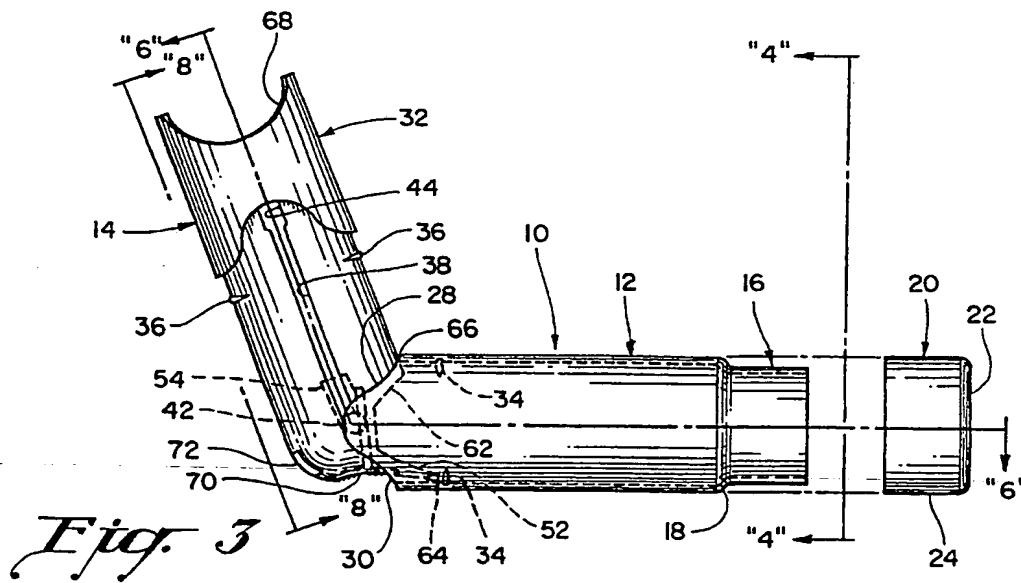
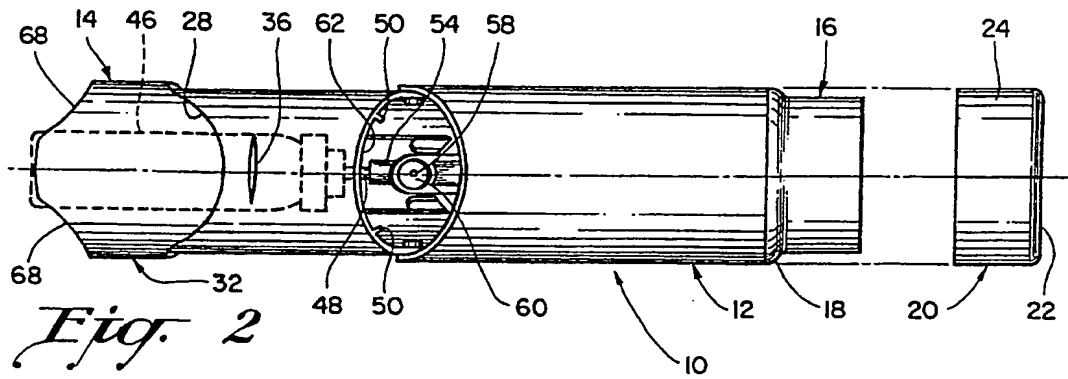
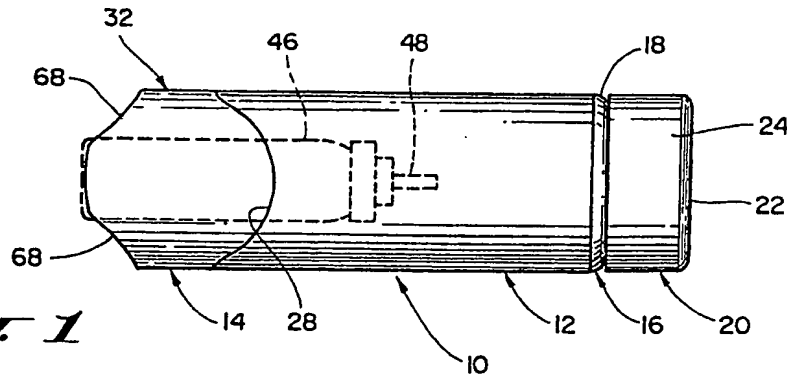
14. The aerosol inhalation device of claim 10 wherein finger-and-thumb engageable depressions are provided at opposite ends of said canister housing as an aid in releasing medicament from said pressurized canister thereof.

15. The aerosol inhalation device of claim 10 wherein longitudinally extending, circumferentially spaced rib members are provided in said canister housing for supporting said pressurized canister of medicament therein.

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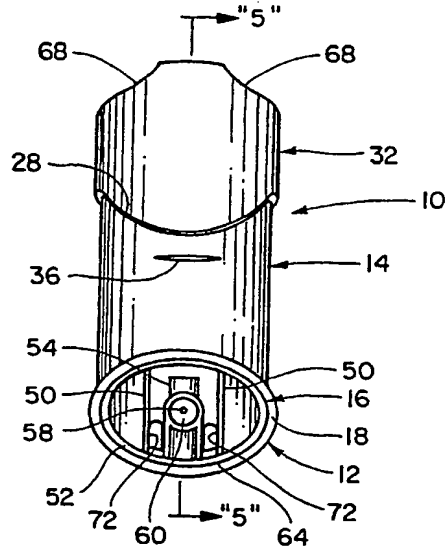
16. An aerosol inhalation device for maximizing delivery of medicament into the lung, said device comprising an elongated expansion chamber open at both ends and elliptical in crosssection, a mouthpiece configuration provided at one end of said expansion chamber, an elongated canister housing elliptical in cross-section and generally telescopically slidable into the other open end of said expansion chamber and open at its end furthest from the expansion chamber for receiving therein a pressurized canister of medicament having an outwardly biased valve stem projecting from the inner end thereof, a valve stem housing having an axially aligned bore provided on an inner end wall of said canister housing for receiving said canister valve stem, a laterally disposed orifice passage formed in said valve stem housing and intersecting the axial bore thereof inwardly of the end of said valve stem with the axis of said orifice passage being disposed at an angle between  $90^\circ$  and  $110^\circ$  from the axis of said axial bore of said valve-stem housing and with an exit end of said orifice passage being generally conical in configuration, a side wall portion of said canister housing opposite said conical configuration of the exit end of said orifice passage being broken away, pin-and-slot means connecting said canister housing to said other open end of said expansion chamber whereby to permit slidable movement of said canister housing from a storage position telescoped within said expansion chamber to an axially-aligned, fully-extended position, said canister housing being pivotal only when in said fully-extended position through between  $70^\circ$  and  $90^\circ$  in one direction only into an operable position wherein the axis of said orifice passage is disposed in axial alignment with the longitudinal axis of said elliptical expansion chamber, interference means between said expansion chamber and said canister housing limiting relative pivotal movement therebetween, and auxiliary air inlet means provided in a side wall portion of said canister housing diametrically opposite said broken-away side wall portion and to the rear of said orifice passage in said valve stem housing.

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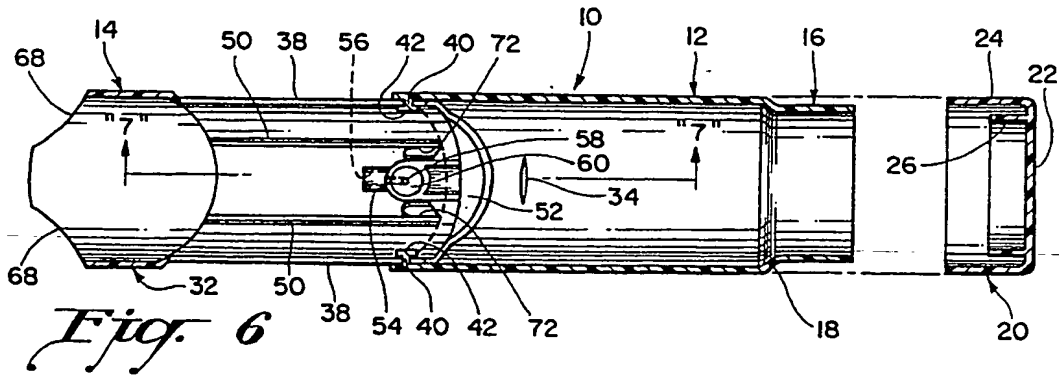
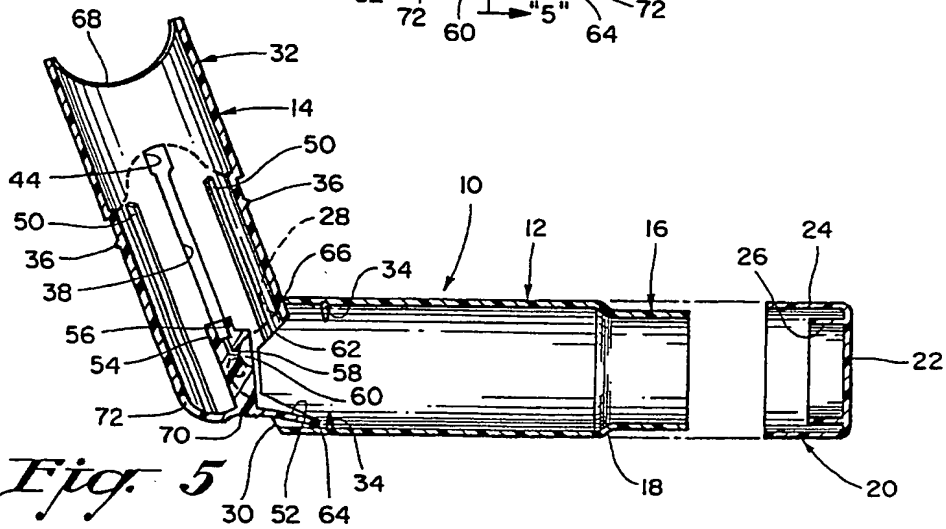


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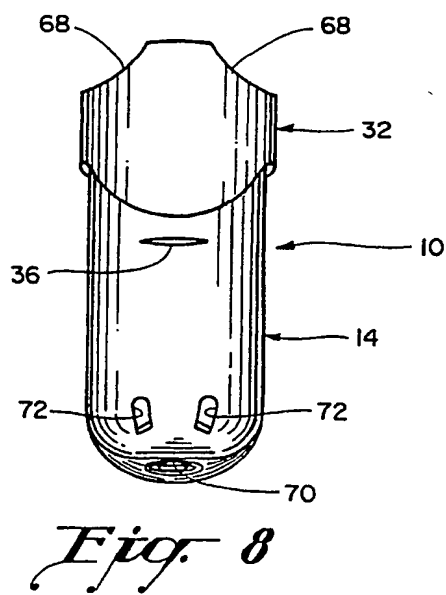
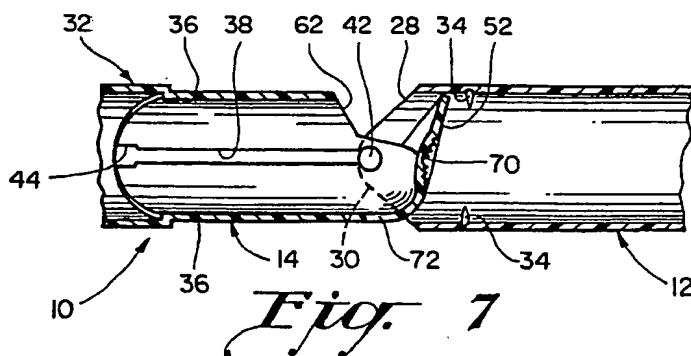
*Fig. 4*



*Fig. 5*



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## INTERNATIONAL SEARCH REPORT

international application No.  
PCT/US92/03945

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(5) :A61M 11/00, 15/00; B67D 5/06; B65D 83/00 US CL :128/200.14,200.23,203.12; 222/182,402.12 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) U.S. : 128/200.14,200.23,203.12; 222/182,402.12 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 3,739,950 (GORMAN) 19 June 1973, See Fig. 1.	1-16
Y	US, A, 3,994,421 (HANSEN) 30 November 1976, See Figs. 1 and 2.	1-16
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* "A" "E" "L" "O" "P"	Special categories of cited documents: document defining the general state of the art which is not considered to be part of particular relevance earlier document published on or after the international filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "G" document member of the same patent family
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Name and mailing address of the ISA/ Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. NOT APPLICABLE		Authorized officer <i>My Means</i> AARON J. LEWIS Telephone No. (703) 308-0858